

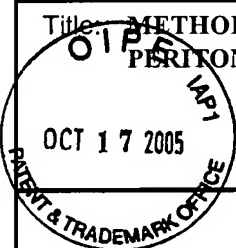
**TRANSMITTAL OF INFORMATION DISCLOSURE STATEMENT**  
(Under 37 CFR 1.97(b) or 1.97(c))

Docket No.  
DI-6121

In Re Application: **Martis et al.**

Application No.	Filing Date	Examiner	Customer No.	Group Art Unit	Confirmation No.
10/789,320	Feb. 27, 2004	A. Ford	29200	1651	9380

Title: **METHODS AND COMPOSITIONS FOR DETECTION OF MICROBIAL CONTAMINANTS IN PERITONEAL DIALYSIS SOLUTIONS**



**Payment of Fee**

(Only complete if Applicant elects to pay the fee set forth in 37 CFR 1.17(p))

- ☒ A check in the amount of **\$180.00** is attached.
- ☒ The Director is hereby authorized to charge and credit Deposit Account No. **02-1818** as described below.
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- ☒ Credit any overpayment.
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Signature of Person Mailing Correspondence
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**\*This certificate may only be used if paying by deposit account.**

Dated: **October 13, 2005**

Signature

**Robert M. Barrett (30,142)**  
Cust. No. 29200

10/19/2005 WASFAW1 00000003 10789320

02 RC:1806

180.00 DP

CC:

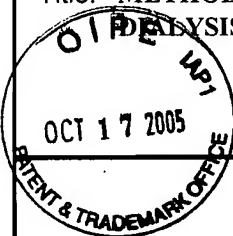
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10/789,320	Feb. 27, 2004	A. Ford	29200	1651	9380

Title: **METHODS AND COMPOSITIONS FOR DETECTION OF MICROBIAL CONTAMINANTS IN PERITONEAL ANALYSIS SOLUTIONS**



Address to:  
**Commissioner for Patents**  
**P.O. Box 1450**  
**Alexandria, VA 22313-1450**

**37 CFR 1.97(b)**

1. ☐ The Information Disclosure Statement submitted herewith is being filed within three months of the filing of a national application other than a continued prosecution application under 37 CFR 1.53(d); within three months of the date of entry of the national stage as set forth in 37 CFR 1.491 in an international application; before the mailing of a first Office Action on the merits, or before the mailing of a first Office Action after the filing of a request for continued examination under 37 CFR 1.114.

**37 CFR 1.97(c)**

2. ☒ The Information Disclosure Statement submitted herewith is being filed after the period specified in 37 CFR 1.97(b), provided that the Information Disclosure Statement is filed before the mailing date of a Final Action under 37 CFR 1.113, a Notice of Allowance under 37 CFR 1.311, or an Action that otherwise closes prosecution in the application, and is accompanied by one of:

☐ the statement specified in 37 CFR 1.97(e);

**OR**

☒ the fee set forth in 37 CFR 1.17(p).



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Martis et al.  
Appl. No.: 10/789,320  
Conf. No.: 9380  
Filed: February 27, 2004  
Title: METHODS AND COMPOSITIONS FOR DETECTION OF MICROBIAL  
CONTAMINANTS IN PERITONEAL DIALYSIS SOLUTIONS  
Art Unit: 1623  
Examiner: A. Ford  
Docket No.: DI-6121 (BBL No. 112713-535)

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

**SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT**

Sir:

In accordance with the provisions of 37 C.F.R. 1.56, 37 C.F.R. 1.97, and 37 C.F.R. 1.98, Applicants request that a citation and examination of the references cited below, and on the attached PTO-1449 form be made during the course of examination of the above-identified application for United States patent. Pursuant to 37 C.F.R. 1.98, copies of all foreign patent documents and non-patent documents are enclosed.

**OTHER DOCUMENTS**

TOURE FATOUMA ET AL. "Icodextrin-induced peritonitis: Study of five cases and comparison with bacterial peritonitis," KIDNEY INTERNATIONAL, vol. 65, no. 2, February 2004 (2004-02), pages 654-660

POVLSEN J. V. ET AL.: "Exposure to the Peptidoglycan Contaminant in Icodextrin May Cause Sensitization of the Patient Maintained on Peritoneal Dialysis." PERITONEAL DIALYSIS INTERNATIONAL, vol. 23, September 2003, pages 509-510

BASILE CARLO ET AL.: "The impact of relapsing sterile icodextrin-associated peritonitis on peritoneal dialysis outcome.: JOURNAL OF NEPHROLOGY, vol. 16, May 2003, pages 384-386

KANNY G ET AL.: "Immunochemical Analysis of Peritoneal Dialysate in a Patient with Hypersensitivity to Icodextrin." PERITONEAL DIALYSIS INTERNATIONAL: JOURNAL OF THE INTERNATIONAL SOCIETY FOR PERITONEAL DIALYSIS, vol. 23, July 2003, pages 405-406

SEOW YING-YING T ET AL.: "Icodextrin-associated peritonitis among CAPD patients," NEPHROLOGY DIALYSIS TRANSPLANTATION, vol. 18, no. 9, September 2003, pages 1951-1952

GLORIEUX GRIET ET AL.: "Specific Characteristics of Peritoneal leucocyte populations during sterile peritonitis associated with icodextrin CAPD fluids." NEPHROLOGY DIALYSIS TRANSPLANTATION, vol. 18, no. 8, August 2003, pages 1648-1653.

MALBERTI F ET AL.: "STERILE PERITONITIS ASSOCIATED WITH THE USE OF ICODEXTRIN SOLUTIONS IN PATIENTS ON PERITONEAL DIALYSIS (PD)" NEPHROLOGY DIALYSIS TRANSPLANTATION, vol. 17, no. Abstracts Supplement 1, 2002, page 307, XP008048088 & XXXIX CONGRESS OF THE EUROPEAN RENAL ASSOCIATION AND THE EUROPEAN DIALYSIS AND TRANSPLANT ASSOCIATION; COPENHAGEN, DENMARK; July 14-17, 2002.

MINORS S ET AL.: "A Sensitive Chemiluminescence Based Immunoassay For Antibody To Staphylococcal Peptidoglycan" JOURNAL OF IMMUNOLOGICAL METHODS, vol. 115, no. 1, 1988, pages 119-125.

Extraneal letter dated May 22, 2002; 2 pages

Wako Pure Chemical Industries, Ltd., Osaka, Japan, 6 pages, published prior to February 27, 2004

Applicants are also submitting herewith a copy of the International Search Report and written opinion associated with International Application No. PCT/US2005/005187 that corresponds to the present application.

Applicants are also submitting herewith another copy of the above-identified Wako Pure Chemical Industries publication. Although Applicants are not aware of the actual publication date, Applicants believe that this reference was published prior to the filing date of the present application as identified above.

Applicants look forward to early and favorable consideration of this matter.

Respectfully submitted,

BY 

Robert M. Barrett (30,142)  
Customer No.: 29200

Dated: October 13, 2005



<b>INFORMATION DISCLOSURE CITATION IN AN APPLICATION</b> (Use several sheets if necessary)  PTO Form 1449	Atty Docket No. DI-6121	Application No. 10/789,320
	Applicant Martis et al.	
	Filing Date Feb. 27, 2004	Group 1651

U.S. PATENT DOCUMENTS							
Examiner's Initials		Document Number	Publication Date	Inventor	Class	Subclass	Filing Date If Appropriate

FOREIGN PATENT DOCUMENTS								
Examiner's Initials		Document Number	Publication Date	Country	Class	Subclass	Translation	
							Yes	No

Examiner's Initials		OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)
		TOURE FATOUMA ET AL. "Icodextrin-induced peritonitis: Study of five cases and comparison with bacterial peritonitis," KIDNEY INTERNATIONAL, vol. 65, no. 2, February 2004 (2004-02), pages 654-660
		POVLSEN J. V. ET AL.: "Exposure to the Peptidoglycan Contaminant in Icodextrin May Cause Sensitization of the Patient Maintained on Peritoneal Dialysis." PERITONEAL DIALYSIS INTERNATIONAL, vol. 23, September 2003, pages 509-510
		BASILE CARLO ET AL.: "The impact of relapsing sterile icodextrin-associated peritonitis on peritoneal dialysis outcome.: JOURNAL OF NEPHROLOGY, vol. 16, May 2003, pages 384-386
		KANNY G ET AL.: "Immunochemical Analysis of Peritoneal Dialysate in a Patient with Hypersensitivity to Icodextrin." PERITONEAL DIALYSIS INTERNATIONAL: JOURNAL OF THE INTERNATIONAL SOCIETY FOR PERITONEAL DIALYSIS, vol. 23, July 2003, pages 405-406

Examiner:	Date Considered:
*Examiner: Initial if citation considered, whether or not citation is in conformance with MPEP Section 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.	

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	Applicant Martis et al.	
	Filing Date Feb. 27, 2004	Group 1651

Examiner's Initials	OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)
	SEOW YING-YING T ET AL.: "Icodextrin-associated peritonitis among CAPD patients," NEPHROLOGY DIALYSIS TRANSPLANTATION, vol. 18, no. 9, September 2003, pages 1951-1952
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